REVIEW OF METAMIZOLE-CONTAINING MEDICINAL PRODUCTS

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INSTITUTIONAL OPINION – SPANISH PAIN SOCIETY (SED – SOCIEDAD ESPAÑOLA DEL DOLOR)

The European Medicines Agency (EMA) has initiated a review of medications containing the painkiller metamizole due to concerns that the current measures to minimize the known risk of agranulocytosis may be insufficient.

SPANISH EXPERIENCE AND RECOMMENDATIONS: Based on our experience in Spain, we have consistently communicated, in line with statements from the Spanish Agency of Medicines and Medical Devices (AEMPS), that there is **no evidence of harm beyond what is already described** in the technical datasheet. In our hands, cases of agranulocytosis or life-threatening risks associated with metamizole consumption are negligible.

Like all medications, metamizole has a long list of potential adverse effects detailed in its technical datasheet. Generally, the use of metamizole is not dangerous, with most adverse effects being mild. However, the most feared severe adverse effect is agranulocytosis, a rapid drop in white blood cells that can be fatal. To mitigate this risk, it is recommended to use metamizole "only for short-term treatments, with a maximum duration of seven days." If longer treatment is necessary, periodic hematological monitoring should be conducted to check white blood cell levels.

There has been ongoing discussion for years about whether there is greater susceptibility among the "population in Northern Europe," with certain genetic factors being studied. However, the available information does not confirm or rule out a higher risk in populations with specific ethnic or genetic characteristics. Some countries, like the United Kingdom and the USA, have withdrawn metamizole from the market due to an unfavorable risk-benefit balance.

AEMPS advises "regular monitoring" for treatments lasting more than a week to detect any immune system alterations. Therefore, it is recommended "not to use metamizole in patients where such monitoring is not feasible," such as tourists visiting Spain. Special caution is also advised for elderly individuals, whose immune systems may be weakened by age.

Recently, AEMPS conducted an evaluation of the drug and concluded that there is no new evidence to support its withdrawal from the market in Spain. This decision partly responds to demands from the Association of Patients Affected by Medications (ADAF), which seeks the withdrawal of metamizole in Spain and compensation for damages suffered by patients. ADAF claims to have knowledge of 350 cases (80 already registered) and 45 documented deaths over the past three decades, primarily among citizens of the UK and Ireland. Last year, ADAF filed a complaint with the National Court against the Ministry of Health for its "inaction" regarding the risks of the drug.

Metamizole, like any drug or analgesic, has therapeutic properties as well as potential adverse effects, ranging from common to rare or very rare, such as agranulocytosis and anaphylactic shock. However, scientific evidence and extensive clinical experience, both in outpatient and hospital settings, support that with proper medical supervision—limited to seven days or extended with close monitoring—it is a safe drug. Therefore, in our opinion, metamizole is being unfairly stigmatized despite its long-standing use and manageable risks, akin to other analgesics.

SOURCES

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Kind regards,

Sociedad Española del Dolor

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